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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,527

Applicant(s)

SCHAEFER ET AL.

Examiner

Lora E. Barnhart

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RD

DETAILED ACTION

The examiner notes that the claims have been amended and agrees that no new matter is added by these amendments. No claims have been added or cancelled. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Prior art references can be found in a prior Office action, unless otherwise noted.

Claim Objections

The amendments to the claims have corrected the claim dependency problem. This objection to the claims is lifted.

Claim Rejections - 35 USC § 112

Claims 40 and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's amendments to these claims have been fully considered, but they are not sufficient to overcome the rejection.

The claims as originally filed recite, "a biological joint construct...[that] is designed as an individual preformed construct." These claims were pointed out in the Office action mailed 12/6/04 as being confusing, because it is "unclear whether these 'designed as' descriptions are limitations on the structure or whether they are simply statements of intended use." The claims have been amended to recite, "a biological joint construct... sized and configured as an individual preformed construct." These amendments amount to a replacement of the word "designed" with the words "sized and configured", and they do not clarify the point of confusion. Specifically, the words

Art Unit: 1651

"designed", "sized", and "configured" could all be considered either verbs (thereby imparting an intended use limitation to the claims) or adjectives (thereby imparting structural limitations to the claims). Clarification is required.

Additionally, the phrase "osteochondral cylinder" in claim 41 remains indefinite, as asserted by the examiner in the prior Office action. Clarification is required. Claims 40 and 41 remain rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

Claims 36, 37, 40, and 41 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. '050 taken in light of Thomas and Boden. Applicant's arguments regarding this rejection have been fully considered, but they are not persuasive. It is noted that no amendments were made to these claims in an effort to overcome the rejection under 35 U.S.C. 102(b).

On the first Office action, the examiner asserted that both the instantly claimed composition and the composition of U.S. '050 teach biological joint constructs produced at least partly *in vitro* that comprise a biocompatible carrier material and chondrocytes and can be successfully implanted into bone defect sites (page 5, paragraph 2). The examiner further asserted that the broad nature of the claims is drawn to "any biological joint construct that, upon implantation, integrates into a bone and leads to the formation of layers of cartilage on the bone's end" (page 6, paragraph 2). The examiner further set forth three specific ways in which the claims lack novelty (page 6, paragraph 2).

The applicant has argued that U.S. '050 is not appropriate prior art because it teaches a "composition", while the instantly claimed construct is an "apparatus" (page

Art Unit: 1651

11, paragraph 2). The examiner disagrees. As was pointed out on the first Office action, the construct **as claimed** is identical the composition of U.S. '050 in terms of structure, method of making, and functionality; because the applicant chooses to consider the claim-designated invention an "apparatus" does not necessarily distinguish it from the prior art teaching. Applicant's assertion that the term "joint construct" connotes some specific structural features not taught in U.S. '050 is not supported by actual facts, since the composition of U.S. '050 is taught as being useful for repairing articular (joint) defects (U.S. '050, column 5, lines 9-11). M.P.E.P. § 2112.01 recites, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established." As outlined on the first Office action, the composition of U.S. '050 is substantially identical in structure, composition, and intended use to the instant composition **as claimed**; a finding of anticipation is clearly proper. In short, applicant's argument fails to comply with 37 CFR 1.111(b) because it amounts to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the **claims** patentably distinguishes them from the references.

The applicant has further argued that U.S. '050 does not teach "*in vitro* lateral sequestration of [two] types of cells", "disjunctive" use of cells, or a composition in which chondrogenic and osteogenic cells are cultured *in vitro* (page 11, paragraph 3), all of which are taught in the specification. These limitations, however, are not recited in the **claims**. According to M.P.E.P. § 2111, the pending claims must be "given their broadest

Art Unit: 1651

reasonable interpretation consistent with the specification. Broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. In *In re Prater* (citations omitted), the court ruled that "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from reading limitations of the specification into a claim, to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim." The court found that applicant was advocating the latter, i.e., the impermissible importation of subject matter from the specification into the claim. As pointed out on the first Office action, the claims read on the matter of U.S. '050, and it is improper to incorporate material limitations from the specification into the claims.

In addition, claim 36 is a product-by-process claim; claims 37, 40, and 41 depend from said claim. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

Applicant's arguments regarding the **process** by which the **claimed composition** is made, therefore, have no bearing on the patentability of the claim-recited invention. The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, **it is the patentability of the product claimed and not of the recited process steps which must be established.**"

We are therefore of the opinion that when the prior art discloses a product which

reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown* (citations omitted).

Finally, applicant's argument that the examiner did not distinguish between "structure and functionality" is unpersuasive. Even if the phrase "biological joint construct" is interpreted as referring to a composition with a specific function not taught or implied by U.S. '050, this argument has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao* and *Kropa v. Robie* (citations omitted).

Applicants have forwarded no arguments regarding the validity of Thomas and Boden and therefore stipulate that Thomas and Boden are appropriate prior art. Claims 36, 37, 40, and 41 remain rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. '050 taken in light of Thomas and Boden.

Claim Rejections - 35 USC § 103

Claims 38 and 42 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. '050 taken in view of U.S. '296, Thomas, and Boden. Applicant's arguments

regarding this rejection have been fully considered, but they are not persuasive. It is noted that no amendments were made to these claims in an effort to overcome the rejection under 35 U.S.C. 103(a).

On the first Office action, the examiner asserted that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the construct of U.S. '050 with the peg of U.S. '296 because the construct of U.S. '050 can be made of any shape and size.

Applicants argue that U.S. '050 does not teach the use of its exemplified composition to repair a damaged joint. This argument is unconvincing for two reasons. In the first place, U.S. '050 in fact provides guidelines for the use of the exemplified composition in the repair of articular (joint) defects (column 5, lines 9-11). In addition, as discussed above, limitations on function and intended use are immaterial to the patentability of the **claimed product**.

Applicants have also argued that since the composition of U.S. '296 is made from "non-biological materials", it could not be combined successfully with the composition of U.S. '050 to arrive at the claim-recited invention. In fact, the examiner did not suggest such a combination, but rather that the construct of U.S. '050 could be fashioned such that it has a peg shape, like that of the composition of U.S. '296. As discussed above, the construct of U.S. '050 can have any shape.

Because the examiner found applicant's arguments regarding U.S. '050 unpersuasive, claims 38 and 42 are still rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. '050 taken in view of U.S. '296, Thomas, and Boden.

Art Unit: 1651

Claims 39, 43, and 44 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. '050 taken in view of U.S. '296, U.S. '660, Dunn et al., Thomas, and Boden. Applicant's arguments regarding this rejection have been fully considered, but they are not persuasive. It is noted that no amendments were made to these claims in an effort to overcome the rejection under 35 U.S.C. 103(a).

Again, applicant's arguments regarding the combination of U.S. '050 and U.S. '660 center on function and intended use, which are immaterial to the patentability of the claim-recited composition. Applicants also contend that the artificial ligament of U.S. '660 could not be combined with U.S. '550 but give no substantive evidence why this should be the case. Applicant's arguments regarding U.S. '660 amount to a mere allegation of patentability. Applicants have forwarded no arguments regarding the validity of Dunn et al. and therefore stipulate that Dunn et al. is appropriate prior art.

Because the examiner found applicant's arguments regarding U.S. '050 unpersuasive, claims 38 and 42 are still rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. '050 taken in view of U.S. '296, U.S. '660, Dunn et al., Thomas, and Boden.

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1651

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lora Barnhart
assistant examiner


IRENE MARX
PRIMARY EXAMINER